Virginia Division of Consolidated Laboratory Services Virginia Environmental Laboratory Accreditation Program

FREQUENTLY ASKED QUESTIONS

PROFICIENCY TESTING UPDATED June 11, 2012

Why is proficiency testing important?

Satisfactory and continuing proficiency testing (PT) is a <u>critical component</u> of the certification or accreditation process under the Virginia Environmental Laboratory Accreditation Program (VELAP). Proficiency testing is necessary to demonstrate a laboratory's ability to satisfactorily perform tests for which it is certified or accredited.

What are the requirements for proficiency testing (PT)?

For proficiency testing requirements, please see the regulations at 1VAC30-45, Part II, Article 3 (1VAC30-45-500 through 1VAC30-45-530) for noncommercial environmental laboratories and 1VAC30-46-210 C for commercial environmental laboratories. 1VAC30-46-210 C incorporates by reference parts of Chapters 2 and 4 of the 2003 NELAC Standards.

A summary of these requirements and additional information are provided below.

What are the PT requirements for VELAP certification or accreditation?

- The laboratory participates in two single blind, single concentration PT studies, where
 available, per year for each Field of Proficiency Testing for which the laboratory wishes
 to maintain certification or accreditation. PT samples are handled (i.e., managed,
 analyzed, reported) in the same manner as real environmental samples utilizing the
 same staff and methods as used for routine analysis of that analyte (procedure,
 equipment, and facilities).
- When analyzing a PT sample, the laboratory must use the same preparation, calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates, and other procedures as used when analyzing routine samples.
- Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document for its own records and provide for DCLS both the investigation and the action taken, upon request.
- A laboratory may not send a PT sample or any portion of a PT sample to another lab for any analysis for which it seeks certification or accreditation.
- Laboratory management or staff may not communicate with any individual at another laboratory (including intra-company communication) concerning the PT sample.
- A laboratory may not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks certification or accreditation.
- Each laboratory must successfully complete two PT studies for *each* requested Field of Certification or Accreditation within the most recent three rounds attempted.

- The PT Studies submitted to VELAP to satisfy the initial application requirements must have been performed within eighteen months of the application date.
- Once a laboratory has been granted certification status, it shall continue to complete PT studies for each PT field of testing and maintain a history of at least two acceptable PT studies for each PT field of testing out of the most recent three.

What is the relationship between Fields of Proficiency Testing and Fields of Certification or Accreditation?

- A "Field of Accreditation" or a "Field of Certification" is defined as an approach to accrediting (certifying) laboratories by matrix, technology/method and analyte/analyte group.
- A "Field of Proficiency Testing" is defined as an approach to offer proficiency testing by matrix, technology/method, and analyte/analyte group.
- The matrices offered under VELAP are nonpotable water, solid and chemical materials, biological tissue, and air and emissions. Drinking water is offered under 1VAC30-46 as a matrix for laboratories that must obtain certification for <u>both</u> drinking water and environmental testing.
- A laboratory must ensure that the matrix of the PT study is the same as that for the Field
 of Certification or Accreditation for which the laboratory is requesting certification or
 accreditation.
- The laboratory must ensure that the method performed in the PT study is the same as the method requested for the Field of Certification or Accreditation requested for certification or accreditation.
- The laboratory must ensure that the PT study is accurately reported to the PT provider using citations or codes for the method for which the laboratory holds certification. Accurate reporting of PT studies to the PT provider, in such a way that correlates with the certification, is a certification requirement.
- A laboratory may perform one PT study for multiple methods under the same technology, e.g., a laboratory may analyze only one PT for several methods using ICP.
 Note that a fail for any analyte is recorded as a fail for all methods when the technology is the same.
- The laboratory should ensure that PT study data are reported to the PT Provider for every certified method when the laboratory performs only one analysis for certification of multiple methods. For example, a laboratory with metals by EPA 200.7 and EPA 6010 in nonpotable water is allowed to analyze the sample one time using ICP by its protocols for either EPA 200.7 or EPA 6010. The lab will report the analysis data once by EPA 200.7 and then again by EPA 6010. The data is transmitted electronically from the PT provider into the VELAP database as it is reported by the laboratory.
- For laboratories holding Drinking Water Accreditation under 1VAC30-46, the laboratory
 must analyze each PT sample by each accreditation method. DCLS requires each
 accredited drinking water field of accreditation to be subjected to proficiency testing on a
 semi-annual basis regardless of the technology.
- For laboratories holding Drinking Water Accreditation under 1VAC30-46, the laboratory must meet the EPA requirement for an 80% passing rate for regulated volatile organic compounds or for disinfection byproducts.

Where can I find a list of the available Fields of Proficiency Testing? Where can I find a list of approved proficiency test providers?

The NELAC Institute website (www.nelac-institute.org) maintains a list of available Fields of Proficiency Testing. To find the list of Fields of Proficiency Testing, click on the "Accreditation" tab and then go to the Proficiency Testing section. Separate tabs contain lists of the Fields of Proficiency Testing and approved proficiency test providers. The Fields of Proficiency Testing are provided in either Excel or Adobe Acrobat format. There are Fields of Proficiency Testing for the following matrices: drinking water, non-potable water, and solid and chemical materials.

Do I need to perform a PT study if I cannot find the appropriate Field of Proficiency Testing on the NELAC website list?

No, a Field of Proficiency Testing that is not on the NELAC Institute approved list is not required to be performed. However a NELAC Provider may offer PT samples that have not been approved by NELAP. Although not required to maintain certification or accreditation, successful participation in proficiency studies provides an external validation to a laboratory's internal quality assurance program. For those Fields of Certification or Accreditation where a PT Study is not available by an approved NELAC provider and no proficiency sample was performed, the VELAP assessor will require additional on-site time with data review.

How do laboratories report PT study results to DCLS and what important steps must laboratories take to ensure successful reporting?

- The PT provider used by the laboratory reports the results of the PT study both to the laboratory and to DCLS. During the initial application phase of VELAP, laboratories are sometimes directly reporting their PT study results to DCLS.
- Once the laboratory has submitted its VELAP application, all proficiency studies <u>must</u> be reported to VELAP directly by the PT provider. The <u>laboratory</u> communicates this request to the PT provider at the time that results are submitted to the PT provider.
- It is the laboratory's responsibility to accurately report PT results to the PT provider, to ensure proper assignment or credit for satisfactory PTs in the laboratory's VELAP records.
- Accurate reporting of results includes the correct designation of the method for which the laboratory holds certification or accreditation for each analyte resulted.
- Failure to accurately report the required method information for each analyte will result in the laboratory receiving a failure for non-participation in the PT.
- When the laboratory holds certification or accreditation for multiple methods for the same analyte, it is the laboratory's responsibility to submit a result to the PT provider for <u>each</u> certified or accredited method.

How do laboratories satisfy the requirement for two studies per year?

- To maintain certification, completion dates of successive proficiency rounds for a given PT Field of Testing are to be approximately six months apart.
- Failure to meet the semiannual schedule is regarded as a failed study. The closing date of the second study must be <u>no later than seven months</u> after the closing date of the first study.
- Note that for the purposes of evaluating PT timelines, a month is defined as a period of time extending from one date to a corresponding date in the next calendar month. For example, from January 15 until July 15 is six months.

What are PT requirements when Fields of Certification are added to a lab's certification?

To add fields of certification (FOC), a laboratory must submit two successful PTs for the requested FOC. These PTs must be no older than 18 months at the time that the change in scope is requested. Once the request is submitted, DCLS expects the laboratory to incorporate proficiency testing for these additional FOCs into the lab's next semi-annual schedule for PT testing. Failure to establish and maintain a semi-annual schedule for the added FOCs will affect the PT history and may jeopardize the certification status.

What happens if my instrument is down when it is time to do my PT study, or for some other reason I cannot perform the PT before there has been a 7 month lapse since the closing date of the previous study?

The laboratory has two options:

- Accept the PT failure for the affected Fields of Certification or Accreditation for nonparticipation, OR
- Voluntarily withdraw the certification or accreditation until such time that the lab is able to resume testing.
 - To re-instate certification or accreditation and resume this testing, the laboratory will successfully analyze a PT sample for the Field of Certification or Accreditation prior to requesting re-instatement.
 - If more than 12 months have elapsed between the close date of the completed PT and the close date of the last PT done prior to the withdrawal, the laboratory must submit two successfully analyzed PTs prior to requesting reinstatement.
 - This option will generally require payment of the \$150 base fee for a change in scope as described in the "Information and Fees for Adding Fields of Certification" FAQ document posted on the VELAP web page.

What happens if a laboratory cannot maintain a successful history of PT studies?

- Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document for its own records and provide for DCLS both the investigation and the action taken, upon request.
- Failure of <u>any</u> two out of the most recent three PT studies for a given Field of Certification or Accreditation could result in <u>decertification or withdrawal</u> of accreditation for the failed fields of testing (See 1VAC30-45 100 or 1VAC30-46 100). To give the laboratory an opportunity to correct this deficiency before decertification or withdrawal of Fields of Certification or Accreditation, DCLS will suspend the certification or accreditation for the affected fields of testing for up to six months.
- Please note that DCLS Standard Operating Procedures regarding suspension will give
 the laboratories a 60 day window before taking final action to suspend failed fields of
 testing. The laboratory can perform additional PT studies during this window and as
 long as any two out of most recent three PT studies have passing scores, then the
 laboratory's field of testing will remain in good standing.
- Suspension cannot exceed six months. If the laboratory has not successfully restored certification or accreditation during the six months following the initial suspension, the Field of Certification of Accreditation will be decertified or withdrawn.

- Certification or accreditation will be restored, as soon as the laboratory successfully demonstrates two PT studies for each suspended Field of Certification or Accreditation within the most recent three rounds attempted.
- Suspended Fields of Certification or Accreditation may not be analyzed/reported.
- If, after being suspended for failure of PT studies, the laboratory's analysis of the next PT study results in three failed PT studies in a row, DCLS, per 1VAC30-45 100 or 1VAC30-46 100, should <u>decertify or withdraw</u> accreditation for that Field of Certification or Accreditation.
- Following decertification or withdrawal/revocation, the laboratory must re-apply for those fields of certification and additional fees will be charged.

Can a laboratory perform supplemental PT Studies?

- A laboratory may elect to participate in supplemental PT studies when the laboratory desires to add Fields of Proficiency Testing to its scope of certification or accreditation, or when a laboratory fails an initial or continuing PT study and wishes to re-establish its history of successful reporting.
- There must be at least 15 calendar days from the closing date of one study to the shipment date of another study for the same PT field of testing.
- When a laboratory has attained certification or accreditation and chooses to perform supplemental PT studies to demonstrate corrective action for an unacceptable or failed study the following criteria apply:
 - The PT study must be obtained from a PT Provider that meets the certification or accreditation requirements of 1VAC30-45 or 1VAC30-46.
 - The PT Provider cannot supply the laboratory with a sample that has been previously sent to the laboratory. The laboratory is responsible for notifying the PT provider that the request is for a supplemental or corrective action study so that the PT provider may provide an appropriate study.
 - The assigned values for all analyses requested by the laboratory may not be equal to zero (exception: qualitative PCB group and qualitative microbiology).

Does DCLS accept revised results from the PT provider?

 DCLS does not accept modifications to analysis results submitted after the close of the study.